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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,080

Applicant(s)

GOIX ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1-11 and 34-37 in Paper No. 9, filed 11/22/03 is acknowledged and has been entered. Claims 12-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-37 are pending. Claims 1-11 and 34-37 are under examination.

Applicant argues that the inventions are all in the same class and therefore, do not require a different search.

Contrary to Applicants' contention, the scope of the search for each separate invention is not limited to the classification exemplified for purpose of the restriction practice. Rather each search status bifurcates to distinct structural requirements that require separate, possibly overlapping but not necessarily coextensive, fields of search and strategy, etc. Specifically, the structural requirements for each apparatus and method differ from the structural requirements for other apparatus and method in the claimed invention. Thereinafter, extensive evaluation of prior art relevancy for each distinct limitation in every claim to evaluate extent of novelty and obviousness between each distinct invention, likewise, differs.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 7 is vague and indefinite in reciting, "a predetermined *analyzing* volume of sample" because it is unclear what Applicant intends to encompass in reciting, "analyzing" as used in the claim. Does Applicant intend a predetermined volume of sample for analysis in the capillary channel". See also claims 6 and 9.

Claims 2-5 and 34-37 have improper antecedent basis problems in reciting, "A particle analyzing apparatus as in claim ...".

Claims 6 and 8-11 have improper antecedent basis problems in reciting, "A particle analyzing apparatus for analyzing a sample as in claim ...".

Claim 5 is ambiguous in relation to claim 1 in reciting, "including a detector for detecting all particles flowing along the capillary tube" because claim 1 appears to recite illumination of light source upon a predetermined volume of sample for detection of fluorescent light emitted by particles (only) in the volume by a detector. Does Applicant intend for this detector to be a second separate detector from the "at least one detector" recited in claim 1.

Claim 6 lacks clear antecedent support in reciting, "said particle detector". Furthermore, claim 6 is vague and indefinite in relation to claims 5 and 1 from which it depends in reciting, "said particle detector detects light scattered by particles in said

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predetermined analyzing volume” because claims 1 and 5 appear to be separate and distinct detectors. Please clarify.

Claim 7 lacks clear antecedent support in reciting, “said detector” and “said flowing particles”. Furthermore, claim 7 is vague and indefinite in relation to claims 5 and 1 from which it depends in reciting, “said particle detector detects a change in impedance caused by ” because claims 1 and 5 appear to be separate and distinct detectors. Please clarify.

Claim 9 is indefinite in reciting, “including a particle detector” because it is unclear what other elements are included in the claim. Also, claim 9 has improper antecedent basis problem in reciting, “a particle detector”.

In claim 34, “predetermining” should be --predetermined--.

Claim 34 is confusing in reciting, “such as to cause substantially all particles to singulate as they pass through the analyzing volume” because it appears that the “analyzing volume” in this instant claim is a portion of the capillary channel whereas in claim 1, it appears to be recited as a portion of the sample being analyzed. Please clarify.

Claim 35 lacks antecedent support in reciting, “said at least one detector means”.

Claim 35 is vague and indefinite in reciting, “a first detector” and “a second detector” because it is unclear how these detectors relate structurally to the detectors recited in claim 1 as well as the detectors recited in claims 5-7 and 9-10. Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5, 8, and 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goix (WO 98/57152).

Goix discloses an apparatus for detecting particles (microparticles) such as bacteria, virus, fungus, and parasitic cysts, i.e. Giardia, or microscopic beads, in fluid samples (see page 5, lines 12-29 and Figures 2, 3, and 4). The apparatus comprises an elongate cylindrical capillary channel (capillary tube) with a predetermined internal cross-sectional area configured to admit particles one at a time, i.e. singulate, as a sample volume passes through analysis area, a pump for drawing sample containing the particles through the channel and flowing the particles along the capillary channel into its other end. The pump may be a syringe or a peristaltic pump (see page 6, lines 10-26). The apparatus further includes a light source (laser) which generates a laser beam for illumination and focus through one or more lenses onto a test volume of the sample being analyzed (see page 7, lines 5-9). The apparatus also includes a detector, i.e. photomultiplier tube, for detecting particles that flow along the capillary tube, the detector having a collecting lens for intercepting (gathering) fluorescent light emitted by particles, and a slit (interference filter(s)) in front of the photomultiplier tube to block unwanted light, i.e. filter out resonant light (see page 7, lines 5-20). The apparatus may optionally have a dichroic beam splitter (diffraction grating) upon which fluorescence

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emissions are gathered and reflected or passed through for receiving and imaging of transmitted or reflected light onto multiple detector array which provides an output signal (see page 7, line 21 to page 8, line 12). A set of interference filters are used to single out fluorescence emission of fluorescent substance used to tag the particles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of Hirako (US 5,135,302).

Goix has been discussed supra. Goix differs from the instant invention in failing to disclose an off-axis detector which detects light scattered by particles in the test

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volume. Goix further differs in failing to disclose a detector which includes a beam blocker for blocking direct light so that detector only receives scattered light.

Hirako discloses an apparatus which includes a capillary channel (flow cell) containing a flow stream of particles which flows one at a time, i.e. singulated, based on hydrodynamic method (see Abstract). The apparatus specifically includes a forward scattered light detector for detecting light scattered by particles in the same direction of light source and an off-axis particle detector, i.e. a right angle scattered light detector for detecting light scattered or radiated in a right angle with respect to the direction of the radiating light (see Figure 2). The apparatus also includes light collecting lenses for intercepting fluorescent light and slits (pinholes) for blocking unwanted light from detectors. Hirako also discloses that the forward scattered light detector includes a beam blocker for blocking direct light so that the detector only receives scattered light.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an off-axis detector as taught by Hirako into the particle analyzing apparatus as taught by Goix because off-axis detectors such as right angle scattered light detectors as taught by Hirako allow for detection of other parameters in a particle or cell such as granularity, which are not otherwise detected using forward axial scattered light detector. One of ordinary skill in the art at the time of the instant invention would have been motivated to further complement the particle analyzing apparatus of Goix with the beam blocker as taught by Hirako because beam blockers assist in blocking direct light; thus, allowing light scatter detectors to receive only desired scattered light.

5. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of Bernstein et al. (US 5,478,750).

Goix has been discussed supra. Goix differs from the instant invention in failing to disclose a detection system wherein a beam splitter receives gathered light and reflects light above a predetermined wavelength and passes light below the predetermined wavelength. Goix further differs from the instant invention in failing to disclose that the predetermined wavelength is 620 nm, the light below the predetermined wavelength is 580 nm, the light above the predetermined wavelength is 675 nm, and that a filter is interposed between the beam splitter and each detector of the detection system.

Bernstein et al. disclose a compact optical system in an analyzer which allows for simultaneous measurement of light absorption at a plurality of wavelengths. Specifically, Bernstein et al. disclose a series of detector assemblies; each detector assembly comprising a beam splitter, an interference filter, and a photodetector. The beam splitter functions to receive gathered light, reflect light above a predetermined wavelength, and transmit (pass) light below a predetermined wavelength (see column 4, lines 39-66).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Bernstein of multiple detection assembly which can be programmed to reflect or transmit at predetermined wavelengths with the

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apparatus as taught by Goix because Bernstein specifically taught application of the compact optical system to any particle analyzing apparatus such as that taught by Goix.

Additionally, it is maintained that wavelength ranges, i.e. 620 nm, below 580 nm, and above 675 nm, are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 36-37 are for any particular purpose or solve any stated problem, and the prior art teaches that wavelength ranges may vary according to the sample being analyzed and the purpose it is used, parameters appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

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6. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of Mochida et al. (US 5,147,607).

Goix has been discussed supra. Goix differs from the instant invention in failing to disclose that the capillary channel is rectangular.

Mochida et al. disclose an apparatus having a fluid flow channel. Mochida et al. disclose that the fluid flow channel may have a variation of cross-sectional shapes such as rectangular, concave, triangular, etc. (see column 7, lines 66-68 and column 8, lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the cylindrical cross-sectional shape of the capillary flow channel as taught by Goix with rectangular cross-sectional shape as taught by Mochida because a rectangular cross-sectional shape of a capillary channel constitutes an obvious variation of cross-sectional shapes in fluid flow channel devices.

7. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of von Behrens et al. (US 5,378,633).

Goix has been discussed supra. Goix differs from the instant invention in failing to disclose using a detector that detects a change in impedance caused by the flowing particles.

Von Behrens et al. disclose optical flow cytometric devices for fluorescence tagging and light scatter measurements of particles such as cell populations. Specifically, von Behrens et al. disclose the device having an impedance channel for

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detecting and enumerating leucocyte nuclei from intact cells (see column 29, lines 27-35). The impedance channel detects a change in electrical impedance across an orifice caused by the flow of particles in the sample (see claim 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the detector of von Behrens that detects a change in impedance with the particle analyzing apparatus of Goix because von Behrens specifically taught application of the impedance channel for measuring electrical impedance of particles such as cells using any optical flow analyzing device such as that taught by Goix.

Remarks

8. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Knollenberg (US 4,728,190) discloses an apparatus for optically detecting light scattered by particles in a fluid sample within passage through a capillary channel (see columns 3-5).

Goix (US 5,798,222) discloses an apparatus which optically detects light scattered by particles using an off-axis detector (photomultiplier tube) set at 90 degree angle of the laser beam (see columns 6-7).

Chupp (US 4,662,742) discloses a flow cytometer apparatus having an off-axis detection system (see Abstract and column 2).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
February 9, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

2/9/03